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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,911	09/18/2001	Arun B. Kulkarni	J&J-2049	8616

27777 7590 01/26/2005

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EXAMINER

LAMM, MARINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/954,911	KULKARNI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 and 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Acknowledgment is made of the amendment filed 10/14/04. Claims pending are 1, 3-9 and 13-17. Claims 1 and 9 have been amended. Claim 17 is new.

#### ***Claim Rejections - 35 USC § 102***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3, 5, 6, 9, 13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagida et al. (US 5,484,816).

Yanagida et al. teach skin treatment compositions containing active agents such as vitamin A, clays such as hectolite and saponite, glycerol, propylene glycol, ethanol, water and acids and/or salts such as citric acid, ascorbic acid, sodium edetate and sodium isoascorbate. See col. 9, lines 9-47; col. 46, Examples 14-2, 14-8. In particular, Example 14-2 anticipates the composition of the instant claims 1, 3, 5, 6, 13, 15 and 16 because it contains water, 10% of glycerol, 5% of ethanol, 0.03% of trisodium edetate, 2% of clay gelling agent (natural montmorillonite) and 0.3% of active agent (vitamin A). Example 14-8 anticipates the composition of the instant claims 1 and 9 as it contains water, glycerol, vitamin A, 0.01% of ascorbic acid, 0.01% of disodium edetate and 0.01% of sodium isoascorbate.

Thus, Yanagida et al. teach each and every limitation of Claims 1, 3, 5, 6, 9, 13, 15 and 16.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 4, 7, 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagida et al. (US 5,484,816).

Yanagida et al. applied as above. The reference does not exemplify the amount of clay as claimed in Claim 4. However, the reference teaches that the amount of clay may be as little as 0.01%, preferably 0.1%, and not exceeding 50% by weight, depending on the desired gelling effect. See col. 9, lines 38-47. It is the Examiner's opinion that the determination of optimal or workable amount of clay within the reference's generic disclosure by routine experimentation is obvious and within the skill of the art. One having ordinary skill in the art would have been motivated to do this to obtain the desired gelling properties of the composition. With respect to Claims 7 and 8, Examples 14-2, 14-8 of Yanagida et al. contain less water-miscible solvent than claimed in the instant claims. However, other examples in the reference contain as much as 30% of glycerol. See Example 9-4. Therefore, the determination of optimal or workable amount of glycerol by routine experimentation is obvious and within the skill of the art. One having ordinary skill in the art would have been motivated to do this to obtain the desired moisturizing properties of the composition. With respect to Claim 17, citric acid is generally taught as suitable stabilizer and exemplified in Example 14-11. See col. 2, lines 17-36. Therefore, it would have been obvious to one having ordinary

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skill in the art at the time the claimed invention was made to use citric acid instead of trisodium edetate in Example 14-2 of Yanagida et al. with a reasonable expectation of obtaining the same stabilizing effect because the reference teaches that these compounds are used for the same purpose.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagida et al. in view of Kamishita (US 4,543,251), supplied by the Applicant.

Yanagida et al. applied as above. While teaching antioxidants and other skin care active agents, the reference does not teach menthol or camphor of the instant claims. However, Kamishita teaches using menthol in topical compositions to "impart a cool feeling to the skin." See col. 3, lines 40-45. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the topical composition of Yanagida et al. such that to add menthol. One having ordinary skill in the art would have been motivated to do this to obtain formulations that impart a cool feeling to the skin as suggested by Kamishita.

### ***Response to Arguments***

6. Applicant's arguments, see pp. 6-7 of the response filed 10/14/04, with respect to the 102(b) rejection of Claims 1, 3-6 and 9 over Han et al. have been fully considered and are persuasive. The rejection has been withdrawn.

7. Applicant's arguments with respect to the Yanagida et al. reference as applied to the amended claims have been fully considered but they are not persuasive.

The Applicant argues that the reference "only teaches compositions that include water-swellable clays and various acids and salts that are present in a concentration much higher than the Applicant's claimed range." (emphasis in original). In response, it is noted that Examples 14-2 and 14-8 teach the compositions containing the amounts of water-swellable clays and various acids and salts within the claimed range as discussed above. In addition, it is noted that stabilizing acids and salts can be present in the compositions of Yanagida et al. in amounts as low as 0.001%. See col. 2, lines 27-36.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

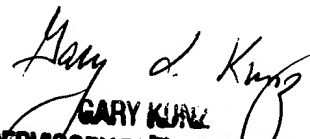
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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1/19/05

